PATENT
Attorney Docket No. PC11835A

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By _____
(Signature of person mailing)
Katerina Georgiou
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Harry R. Howard, Jr. :

APPLICATION NO.: 10/075,847 : Examiner: L. Hong

FILING DATE: February 13, 2002 : Group Art Unit: 1624

TITLE: COMBINATION TREATMENT FOR ANXIETY AND DEPRESSION :

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the Restriction Requirement dated September 26, 2003, wherein the Examiner required restriction of the claims and an election of species, Applicant elects, with traverse, the invention of Group I. Regarding the election of species, Applicant elects the second compound referred to in claim 5 of the present application, specifically, [2-(3,4-Dichlorophenoxy)-5-fluorobenzyl]-methylamine.

Applicant presumes that the election of species is for search purposes only and is not intended to restrict the scope of the claims that ultimately will be examined in the present application. To the extent that Applicant is mistaken in his presumption, that is, to the extent that the Examiner intends that Applicant prosecute only one species in the present application, Applicant traverses the restriction requirement in this regard as well.

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REMARKS

Claims 1-30 are pending in the above-identified application. The Examiner has subjected claims 1-30 to a restriction requirement and election of species. The Examiner asserts that the inventions of Groups I-VII are distinct. By this response, Applicant has elected, with traverse, the invention of Group I and has made an election of species as indicated above. As discussed above, to the extent that the Examiner requires that Applicant prosecute only one species in the present application, Applicant traverses the Examiner's restriction requirement in this regard as well.

At the outset, Applicant wishes to note the following. Claims 1 and 2-5 of the present application relate to pharmaceutical compositions relating to compounds of the Formula I. Claims 1 and 6-18 of the present application relate to pharmaceutical compositions relating to compounds of the Formula II. Claims 1 and 19-21 of the present application relate to pharmaceutical compositions relating to SRIs (*i.e.*, compounds of the Formula I and compounds of the Formula II). Also, claims 22, 23 and 30 of the present application relate to methods of treatment relating to compounds of the Formula I. Claims 22, 24 and 29 of the present application relate to methods of treatment relating to compounds of the Formula II. Claims 22 and 25-28 of the present application relate to methods of treatment relating to SRIs (*i.e.*, compounds of the Formula I and compounds of the Formula II).

As a preliminary matter, Applicant submits the following. Since, as noted above, claims 6-18 relate to pharmaceutical compositions relating only to compounds of the Formula II (and not to compounds of the Formula I), Applicant presumes that in electing the invention of Group I, which Group includes the aforementioned claims 6-18 as well as claims 1-5 and 19-21, Applicant has elected to prosecute, in the present application, pharmaceutical compositions relating to compounds of the Formula I and Formula II.

Applicant traverses the Restriction Requirement for the reasons discussed below. However, should the Examiner nonetheless maintain the Restriction Requirement, Applicant submits that, at the very least, Applicant should be allowed to prosecute, in the same application, the subject matter of Groups II and V along with the subject matter of Group I (that was elected with traverse). Applicant submits

that it is not overly burdensome to allow Applicant to prosecute the subject matter of Groups I, II and V in the same application.

Evidencing Applicant's position is U.S. Patent Serial No. 6,410,736, issued June 25, 2002 that relates to compounds of the Formula II (referred to specifically in claims 1 and 6-18 (and in claims 22, 24 and 29) of the present application). The '736 patent includes a claim 1 directed to the compound of Formula I, which compound is referred to in the present application as the compound of Formula II. Claim 1 of the '736 patent relates to the compound of Formula I (Formula II in the present application) wherein, *inter alia*: (1) rings A and B are phenyl and R1, R2, R3 and R4 do not form a ring – Group I; (2) rings A and B are phenyl and R2 and R3 form a ring – Group V; and (3) rings A and B are naphthyl and R1, R2, R3 and R4 do not form a ring – Group II. Accordingly, in view of the scope of the allowed subject matter in the '736 patent, Applicant submits that examination of Groups I, II and V in the present application is not overly burdensome. Applicant further submits that, at the very least, the examination of Groups I and II, both classified, as indicated by the Examiner, within class 564, is not overly burdensome.

As discussed previously, Applicant also traverses the restriction requirement to the extent that the required election of species is not for search purposes only. Applicant submits that it is certainly not overly burdensome to allow Applicant to prosecute more than one species in the present application.

Applicant reserves the right to file any divisional application(s) directed to any non-elected subject matter in the present application.

However, the above comments notwithstanding, Applicant emphatically traverses the Examiner's requirement for restriction and requests reconsideration in view of the following remarks.

Applicant respectfully requests that the Restriction Requirement be withdrawn since it is not in compliance with 35 U.S.C. §121. 35 U.S.C. §121 provides that the Commissioner may restrict an application when two or more independent and distinct inventions are found within one application. MPEP §807.01 defines independent as follows: The term "independent" (*i.e.*, not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are not connected in design, operation or effect.

Groups I-VII are not independent. Groups I-VI relate to compositions containing an SRI (serotonin reuptake inhibitor) in combination with a GABA-A alpha 2/3 agonist. The SRIs referred to in the present application exhibit serotonin reuptake inhibition activity and can be described by a generic formula *i.e.*, as described for the compound of Formula I and the compound of Formula II. Group VII relates to Groups I-VI as a method of treating anxiety or depression in a mammal by administering the SRI, *i.e.*, a compound of the Formula I or Formula II, and the GABA-A alpha 2/3 agonist referred to in the subject matter of Groups I-VI. Thus, the subject matter of Groups I-VII is clearly interrelated and interdependent, and not "independent and distinct."

Therefore, because the subject matter of Groups I-VII is interdependent, and not independent, the subject matter of Groups I-VII cannot be considered "independent and distinct" so as to justify the Restriction Requirement. Applicant therefore respectfully submits that the Restriction Requirement is improper and cannot be maintained.

The Restriction Requirement also seems to suggest that a prior art search requiring search in more than one Patent Classification System is sufficient criteria for maintaining a restriction to allegedly different patentable inventions. This is in error.

Reliance on the classification of the subject matter in each of the groups does not establish independence and distinctness, the criteria of 35 U.S.C. §121 discussed previously. The classification system has no statutory recognition as evidence of whether alleged separate patent inventions are independent and distinct. The classification system is only an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between the various aspects of Applicant's unitary invention, because the classification system exhibits considerable overlap in technical definitions. In particular, the definitions of subclasses in the classification system do not prevent an Examiner from basing patentability decisions regarding subject matter he assigns to one group on patent references found in the subclass(es) with which he associated other subject matter.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. Such considerations have nothing to do with whether subject matter assigned to different groups is "independent and distinct," as these terms are used in 35 U.S.C. §121.

Thus, basing restriction requirements on the classification system is improper.

In view of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the Restriction Requirement, and provide an Action on the merits with respect to all of the subject matter of the claims of the present application.

Respectfully submitted,

Date: December 24, 2003

Donna R. Grossu
Attorney for Applicants
Reg. No. 47,284

Pfizer Inc
Patent Department
150 East 42nd Street, 5th Floor
New York, NY 10017-5755
(212) 733-5154